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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,507	04/28/1999	MAX CYNADER	230018.401C1	5640

22504 7590 06/28/2004

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EXAMINER	
MARTINELL, JAMES	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/301,507	CYNADER ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 23-62* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 23-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-7 and 23-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Nos. 5 and 8.

The disclosure is objected to because of the following informalities: The separate parts of Figure 5 (*i.e.*, A-V) are not included in the Brief Description of the Drawings (page 11 of the specification). This is the basis for the objection to the drawings (see item 10 on from PTO-326 of this Office action).

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 and 28 of copending Application No. 10/355,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/355,716 embrace SEQ ID NO: 74 of the claims in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 57-62 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (e.g., Office action mailed June 4, 2002, page 2). Applicants' arguments (response filed December 23, 2003, pages 4-6) and the declaration by Dr. Cynader filed under 37 CFR § 1.132 (December 23, 2003) have been considered and are not

convincing. Neither Suarez-Merino et al (Hum. Mut. 17(6), 523 (2001) nor Hiraoka et al (J. Hum. Gen. 46: 178 (2001)) has been considered because these references are not of record. The argument and the declaration (see items 6-9) are that one of skill in the art at the time the invention was made would find the utility of SEQ ID NO: 74 to be readily apparent because SEQ ID NO: 74 shares enough sequence identity with the Norrie disease gene disclosed in Chen et al (Nature Genetics 1: 204 (1992)). This argument is unconvincing for two reasons. First, the gene disclosed in Chen et al is not disclosed as being definitively the gene that causes Norrie disease, but as a candidate gene for Norrie disease (*e.g.*, see page 207, first sentence of the "Discussion" section. Second, one of skill in the art would not have considered SEQ ID NO: 74 to encode for the Norrie gene. The alignment attached to the declaration filed December 23, 2003 as Exhibit I shows that in the reading frame that matches the reading frame of the gene disclosed in Chen et al contains no fewer than four termination codons (see SEQ ID NO: 74 at positions 104-106, 170-172, 197-199, and 215-217). Thus one of skill in the art would readily recognize that SEQ ID NO: 74 could not encode a complete polypeptide that would be comparable to the Chen et al Norrie disease gene. The most that SEQ ID NO: 74 can encode is 24 amino acids of 133 amino acids of the Chen et al sequence for a total sequence identity (even without penalties for mismatches and gaps) of 18.1%. The declaration at item 9 states, "It is quite possible that even with only one-third of its sequence homologous to the Norrie gene, the gene encoded by SEQ ID NO: 74 still retains enough similarity with the Norrie gene to encode a protein that is functionally identical to the gene referenced by Chen et al." It is shown hereinabove that the one-third sequence "homology" figure is an overestimate. The legal standard for patentable utility under 35 USC § 101 is not what one of skill in the art might find to be "quite possible", but what is readily apparent as having utility (see *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966)).

Claims 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of

record (e.g., Office action mailed June 4, 2002, page 2). The discussion in the previous rejection hereinabove is incorporated here.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

James Martinell, Ph.D.
Primary Examiner
Art Unit 1631
6/24/04